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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/055,179

01/23/2002

Jose R. Carranza

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07/02/2004

CARDICA, INC.

900 SAGINAW DRIVE

REDWOOD CITY, CA 94063

EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/055,179	Applicant(s) CARRANZA ET AL. <span style="float: right;">CN</span>	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 16-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41,42,44 and 45 is/are allowed.
- 6) ☒ Claim(s) 1-3,6,9-12,14 and 15 is/are rejected.
- 7) ☒ Claim(s) 4,5,7,8 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 11, 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,695,504 to Gifford III et al.

Gifford discloses a system for preparing a graft vessel comprising a functional package comprising a tray with at least one recess (Column 69 lines 45-62), an assembly held in at least one recess, said assembly comprising a crown and an anastomosis device connected to said crown (100), a pull-through tool (120) comprising a tube, a poke-through tool (111), an anastomosis tool (118) comprising a passage; wherein at least one recess is configured to hold a biocompatible fluid (Column 69 lines 45-62).

Regarding the limitation “a tray with at least one recess”, Isbey, Jr. (U.S. Patent No. 4,501,363) teaches that surgical kits include a tray with at least one recess (FIG. 1 and Column 1 lines 5-34) in order to store surgical supplies used during and after a procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the kit of Gifford with a tray with at least one recess since it is well known in the surgical arts to provide a tray with recesses as a part of a surgical kit.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford III, et al. '504 in view of WO 01/91628 to Podmore et al.

Gifford discloses the claimed invention except for the detachable eversion shield held on said crown. Podmore teaches that an eversion shield is provided in order to protect the graft from premature puncturing by the tines of the anastomosis device (Page 20 lines 12-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Gifford with the eversion shield of Podmore in order to protect the graft vessel from premature puncturing by the tines of the anastomosis device.

***Allowable Subject Matter***

5. Claims 4, 5, 7, 8, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

6. Applicant's arguments filed March 18, 2004 have been fully considered but they are not persuasive.

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7. Applicant argues that Gifford '504 does not disclose "a tray in which at least one recess is defined...wherein at least one recess is configured to hold a biocompatible fluid." Gifford does disclose a kit (Column 69 lines 45-62). A kit may inherently include a package with at least one recess. A kit is considered to be a package to hold a group of instruments for a surgical procedure. Therefore, the rejection over Gifford '504 is proper.

8. Applicant argues that Gifford does not disclose a pull-through tool. Gifford's pull-through tool meets all the claimed structural limitations of claims 2 and 3. Claim 2 claims a pull-through tool configured to be held in said crown and claim 3 claims that said pull-through tool comprises a tube, wherein at least a portion of said tube is held in said crown. The applicant argues that Gifford's vessel punch 120 is not a pull through tool. However, the vessel punch is pulled through the vessel to create an opening, and therefore is considered to be a pull-through tool.

9. Applicant argues that Gifford does not disclose a poke-through tool. Claim 6 claims a poke-through tool held in at least one said recess. The leg (111) of Gifford pokes through the vessel wall (FIG. 5B). Therefore, the legs 111 may be considered to be a poke-through tool. Therefore, the rejection over Gifford '504 is proper.

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Podmore teaches that eversion shields are provided to shield against premature puncturing (Page 20 lines 12-35).

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11. In response to applicant's argument that Podmore teaches that an eversion shield is provided to prevent premature puncturing, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

### ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter  
Examiner  
Art Unit 3731

*JRB*  
jrb

*David O. Reip*  
DAVID O. REIP  
PRIMARY EXAMINER